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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,366	08/20/2001	Sandra M. Sims	3523/2/US	4928

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,366

Applicant(s)

SIMS, SANDRA M.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Detailed Action

The following is responsive to Applicant's amendment and declaration under 37 CFR 1.131 received Nov. 3, 2003.

No claims are cancelled. No new claims are added. Claims 1-30 are currently pending.

The previous rejection of claims 22-30 under 35 USC 112, paragraph 1, set forth in pages 2-3 of the office action mailed Aug. 1, 2003 is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

With respect to the rejection of claims 1-30 under 35 USC 103(a) set forth in pages 3-6 of the office action mailed Aug. 1, 2003, Applicant's amendment and the remarks contained therein as well as the declaration filed under 37 CFR 1.131 are sufficient to overcome the rejection with respect to the WO '387 reference only. The Examiner respectfully submits that claims 1-30 stand rejected under 35 USC 103(a) over Barbachyn et al. in view of Hillard.

Applicant argues that the Hillard reference is a report written by a student at Kalamazoo College describing research conducted at Pharmacia & Upjohn Co. The reference is not available as prior art under section 102(b). Concerning 35 USC 102(a), Applicant asserts that the reference was not publicly known at the time of the priority date of the instant application. The reference was only submitted/described to professors at Kalamazoo College in February 2000. However, these professors were under a contractual obligation to keep the contents of the reference confidential. Therefore, the Hillard reference is not considered prior art under section 102.

Said arguments have been considered but are not found to be persuasive.

The Examiner maintains that the Hillard reference continues to be available as prior art under section 102(a). Applicant's arguments that the Hillard reference was not "publicly known" and only available to professors under a contractual confidentiality agreement appear to be conclusive and unsupported by facts. The Examiner submits that such assertions should be supported by facts in the form of a declaration or affidavit. The rejection is respectfully maintained and claims 1-30 stand rejected.

Claim Rejections-35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a pharmaceutical composition for administration to a subject having or at risk of infective disease. The claimed composition fails to meet the requirement for an adequate written description of the claimed invention as required by 35 USC, 112, paragraph 1. There is insufficient descriptive support for the generic limitation "infective disease", which may include diseases caused by agents ranging from bacteria to viruses to fungi to parasites. Furthermore, the claimed composition includes the treatment of an unspecified disease.

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Other than infective diseases caused by gram-positive bacteria, anaerobic bacteria and acid-fast bacteria, there is no evidence, which indicates that other treatable diseases, were known to Applicant (please see the specification page 6). In the absence of some understanding of the diseases to be treated one of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed composition.


Conclusion

Claims 1-30 stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Mon-Fri from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

CDM 
Jan. 23, 2004


Cybille Delacroix-Muirheid
Patent Examiner Group 1600